Caldera Medical, Inc. T-Sling
K050516 5

510(k) Summary

FEB 3 2006

Date of Summary:	January 19, 2006
Applicant:	Bryon L. Merade, CEO Caldera Medical, Inc. 28632 Roadside Drive, Suite 260 Agoura Hills, CA 91301 Tel: (866) 422-5337 Fax: (818) 879-6556
Contact:	Marla Kengen, Project Leader Caldera Medical, Inc. 28632 Roadside Drive, Suite 260 Agoura Hills, CA 91301 Tel: (866) 422-5337 Fax: (818) 879-6556 marla@calderamedical.com
Device Name:	Surgical Mesh (878.3300)
Trade Name:	T-Sling
Common Name:	Surgical Mesh
Classification:	Class II
Predicate Devices:	Herniamesh T-Sling – K020652 Tyco Healthcare IVS Tunneller – K010035 Ethicon TVT – K012628
Device Description:	The T-Sling is made of monofilament polypropylene warp knitted into composite mesh construction. The T-Sling is a sterile, single-use pubourethral sling for the treatment of stress urinary incontinence (SUI).
Indications for Use:	The T-Sling is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2014

Marla Kengen
Project Leader
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, California 91301

Re: K050516
Trade/Device Name: T-Sling
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OTN
Dated (Date on orig SE ltr): November 28, 2005
Received (Date on orig SE ltr): December 19, 2005

Dear Marla Kengen:

This letter corrects our substantially equivalent letter of February 3, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known) K050516

Device Name: T-Sling

Indications For Use:

The T-sling is intended to be used in females to position a polypropylene mesh for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Herbert P. Lerner -S
2014.03.27 13:33:36 -04'00'

Prescription Use__x OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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